



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Dr. Nisar A. Shaikh  
Director of Quality Systems  
Spectral Diagnostics Inc.  
135 The West Mall  
Toronto, Ontario  
Canada M9C 1C2

MAR 19 2003

Re: k030057  
Trade/Device Name: Spectral Cardiac STATus™ CK-MB-Myoglobin/Troponin I 3-in-1  
test  
Regulation Number: 21 CFR § 862.1215  
Regulation Name: Immunoassay Method, Troponin Subunit, Chromatographic  
Separation, CPK Isoenzymes  
Regulatory Class: II  
Product Code: MMI, JHT, DDR  
Dated: January 3, 2003  
Received: January 7, 2003

Dear Dr. Shaikh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

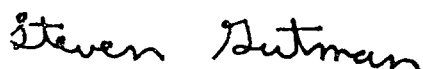
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of In Vitro Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

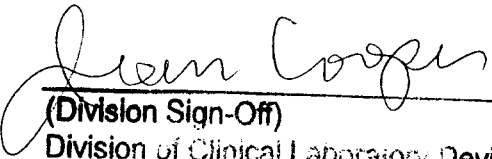
Spectral Diagnostics Inc.  
Spectral Cardiac STATus™ CK-MB/Myoglobin/Troponin I 3-in-1  
510(k) Notification

K030057

**510(k) Number (if Known) :** Not Known at this time

**Device Name:** Spectral Cardiac STATus™ CK-MB/Myoglobin/Troponin I 3-in-1  
test

**Indications for Use:** For the qualitative determination of CK-MB, myoglobin, and cardiac troponin I in human whole blood, plasma or serum as an aid in the diagnosis of acute myocardial infarction in emergency room, critical care, point-of-care, and hospital settings.

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K030057

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER  
PAGE IF NEEDED)

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Professional Use: \_\_\_\_\_

OR

Prescription Use: X  
(Per 21 CFR 801.109)

Over the counter use: \_\_\_\_\_  
(Optional Format 1-2-96)